Bobby Jindal
GOVERNOR

STATE OF LOUISIANA
DEPARTMENT OF HEALTH AND HOSPITALS

LOUISIANA
Department of HEALTH and HOSPITALS
Alan Levine
SECRETARY

Dear Laboratory Director:

On February 28, 1992 the Department of Health and Human Services published regulations in the Federal Register implementing the Clinical Laboratory Improvement Amendments (CLIA) of 1988. According to the regulations every facility that tests human specimens "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" must meet these requirements. CLIA applies to any facility performing laboratory testing as outlined above regardless of the number of tests performed or whether they are charging for the testing. In addition, CLIA requires financing of all regulatory costs through fees assessed to laboratories.

Registration with the CLIA program is required prior to performing and reporting test results. The enclosed CLIA application (Form HCFA-116) and attachment must be completed with the necessary information in order to receive CLIA certification. (NOTE: The CLIA identification number should be left blank as this will be assigned when the application form is processed.) Upon return of the completed HCFA-116 form to the State Agency, a fee remittance coupon will be issued indicating the CLIA identification number, the amount due for the certificate, and a compliance fee for survey if applicable. The appropriate certificate will be issued upon receipt of full payment.

If you have any questions regarding completion of the HCFA-116 form, please contact the State Agency at (225) 342-9324.

To avoid delay in processing, return all enclosed forms to the State Agency as follows:

Staci Glueck
DHH/Health Standards Section
P. O. Box 3767
Baton Rouge, LA 70821-3767

Sincerely,

Erin Rabalais, RN
Manager

Enclosure

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION (FORM CMS-116)

INSTRUCTIONS FOR COMPLETION

CLIA requires every facility that tests human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, a human being to meet certain Federal requirements. If your facility performs tests for these purposes, it is considered, under the law, to be a laboratory. CLIA applies even if only one or a few basic tests are performed, and even if you are not charging for testing. In addition the CLIA legislation requires financing of all regulatory costs through fees assessed to affected facilities.

The CLIA application (Form CMS-116) collects information about your laboratory's operation which is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. This information will also provide an overview of your facility's laboratory operation. All information submitted should be based on your facility's laboratory operation as of the date of form completion.

NOTE: WAIVED TESTS ARE NOT EXEMPT FROM CLIA. FACILITIES PERFORMING ONLY THOSE TESTS CATEGORIZED AS WAIVED MUST APPLY FOR A CLIA CERTIFICATE OF WAIVER.

NOTE: Laboratory directors performing nonwaived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA requirements. Proof of these requirements for the laboratory director must be provided and submitted with the application. Information to be submitted with the application include:

- **Verification of State Licensure, as applicable**
- **Documentation of qualifications:**
  - **Education (copy of Diploma, transcript from accredited institution, CMEs),**
  - **Credentials, and**
  - **Laboratory experience.**

Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of their education to education obtained in the United States. Failure to submit this information will delay the processing of your application.

ALL APPLICABLE SECTIONS MUST BE COMPLETED. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED AND WILL BE RETURNED TO THE FACILITY. PRINT LEGIBLY OR TYPE INFORMATION.

I. GENERAL INFORMATION

For an initial applicant, check "initial application". For an initial survey or for a recertification, check "survey". For a request to change the type of certificate, check "Change in certificate type". For all other changes, including change in location, director, etc., check "other changes".

For an initial applicant, the CLIA number should be left blank. The number will be assigned when the application is processed. Be specific when indicating the name of your facility, particularly when it is a component of a larger entity; e.g., respiratory therapy department in XYZ Hospital. For a physician's office, this may be the name of the physician. **NOTE: The information provided is what will appear on your certificate.**

Facility street address must be the actual physical location where testing is performed, including floor, suite and/or room, if applicable. **DO NOT USE A POST OFFICE BOX NUMBER OR A MAIL DROP ADDRESS FOR THE NUMBER AND STREET OF THE ADDRESS.** If the laboratory has a separate mailing address, please complete that section of the application.

NOTE: For Office Use Only—Date received is the date the form is received by the state agency or CMS regional office for processing.

II. TYPE OF CERTIFICATE REQUESTED

When completing this section, please remember that a facility holding a—

- **Certificate of Waiver** can only perform tests categorized as waived;*
- **Certificate for Provider Performed Microscopy Procedures** (PPM) can only perform tests categorized as PPM, or tests categorized as PPM and waived tests;*
- **Certificate of Compliance** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the applicable CLIA quality standards are met; and
- **Certificate of Accreditation** can perform tests categorized as waived, PPM and moderate and/or high complexity tests provided the laboratory is currently accredited by an approved accreditation organization.**

*A current list of waived and PPMP tests may be obtained from your State agency. Specific test system categorizations can also be reviewed via the Internet on *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm*.

**If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

III. TYPE OF LABORATORY

Select the type of laboratory designation that is most appropriate for your facility from the list provided. If you cannot find your designation within the list, contact your State agency for assistance.

IV. HOURS OF ROUTINE OPERATION

Provide only the times when actual laboratory testing is performed in your facility. Please use the HH:MM format.

V. MULTIPLE SITES

You can only qualify for the multiple site provision (more than one site under one certificate) if you meet one of the CLIA requirements described in 42 CFR 493.

VI. WAIVED TESTING

Indicate the estimated total annual tests volume for all waived tests performed.

VII. PPM TESTING

Indicate the estimated annual test volume for all PPM tests performed.

VIII. NON-WAIVED TESTING *(INCLUDING PPM)*

The total volume in this section includes all non-waived testing, including PPM tests previously counted in section VII. Follow the specific instructions on page 3 of the Form CMS-116 when completing this section. (Note: The Accrediting Organization column should reflect accreditation information for CLIA purposes only; e.g., CAP, etc.).

IX. TYPE OF CONTROL

Select the type which most appropriately describes your facility.

X. DIRECTOR OF ADDITIONAL LABORATORIES

List all other facilities for which the director is responsible.

Note that for a Certificate of PPM, Certificate of Compliance or Certificate of Accreditation, an individual can only serve as the director for no more than five certificates.

Once the completed Form CMS-116 has been returned to the applicable State agency and it is processed, a fee remittance coupon will be issued. The fee remittance coupon will indicate your CLIA identification number and the amount due for the certificate, and if applicable the compliance (survey) or validation fee. If you are applying for a Certificate of Compliance or Certificate of Accreditation, you will initially pay for and receive a Registration Certificate. A Registration Certificate permits a facility requesting a Certificate of Compliance to perform testing until an onsite inspection is conducted to determine program compliance; or for a facility applying for a Certificate of Accreditation, until verification of accreditation by an approved accreditation organization is received by CMS.

If you need additional information concerning CLIA, or if you have questions about completion of this form, please contact your State agency.

TESTS COMMONLY PERFORMED AND THEIR CORRESPONDING LABORATORY SPECIALTIES/SUBSPECIALTIES

HISTOCOMPATABILITY
HLA Typing (disease associated antigens)

SYPHILIS SEROLOGY
RPR
FTA, MHATP

GENERAL IMMUNOLOGY
Mononucleosis Assays
Rheumatoid Arthritis
Febrile Agglutins
Cold Agglutinins
HIV
Antibody Assays (hepatitis, herpes, etc.)
ANA Assays

PARASITOLOGY
Direct Preps
Ova and Parasite Preps
Wet Preps

CHEMISTRY
Routine Chemistry
Albumin
Ammonia
Alk Phos
Bilirubin, Total
Bilirubin, direct
Calcium
Chloride
CO2, total
Ferritin
Glucose
Iron
Magnesium
pH
pO2
pCO2
PSA
Sodium
Vitamin B12
ALT/SGPT
AST/SGOT
Amylase
BUN
CK/CK isoenzymes
Cholesterol, total
Creatinine
Folate
HDL Cholesterol
LDH
LDH isoenzymes
Phosphorous
Potassium
Protein, total
GGT
Troponin
Triglycerides
Uric acid

Urinalysis
Automated urinalysis
Urinalysis with microscopic analysis
Urine specific gravity by refractometer
Urine specific gravity by urinometer
Urine protein by sulfasalicylic acid

BACTERIOLOGY
Gram Stains
Cultures
Sensitivities
Strep Screens
Antigen assays
(H. pylori, Chlamydia, etc.)

MYCOBACTERIOLOGY
Acid Fast Smears
Mycobacterial Cultures
Mycobacterial Sensitivities

MYCOLOGY
Fungal Cultures
DTM
KOH Preps

VIROLOGY
RSV
HPV assays
Cell cultures

Endocrinology
TSH
Free T4
Total T4
Trilodothyronine (T3)
Serum-beta-HCG

Toxicology
Acetaminophen
Blood alcohol
Carbamazephine
Digoxin
Ethosuximide
Gentamycin
Lithium
Phenobarbitol
Phenytoin
Primidine
Procainamide
NAPA
Quinidine
Salicylates
Theophylline
Tobramycin
Valproic acid

HEMATOLOGY

WBC count
RBC count
Hemoglobin
Hematocrit (Other than spun micro)
Platelet count
Differential
Activated Clotting Time
Prothrombin time
Partial thromboplastin time
Fibrinogen
Reticulocyte count
Manual WBC by hemocytometer
Manual platelet by hemocytometer
Manual RBC by hemocytometer
Sperm count

RADIOBIOASSAY

Red cell volume
Schilling's test

IMMUNOHEMATOLOGY

ABO group
Rh(D) type
Antibody Screening
Antibody Identification
Compatability testing

PATHOLOGY

Dermatopathology
Oral pathology
PAP smear interpretations
Other cytology tests
Histopathology

CYTOGENETICS

Fragile X
Buccal smear

GUIDELINES FOR COUNTING TESTS FOR CLIA

- For **histocompatibility**, each HLA typing (including disease associated antigens), HLA antibody screen, or HLA crossmatch is counted as one test.
- For **microbiology**, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per specimen regardless of the extent of identification, number of organisms isolated and number of tests/procedures required for identification.
- Testing for allergens should be counted as one test per individual allergen.
- For **chemistry** profiles, each individual analyte is counted separately.
- For **urinalysis**, microscopic and macroscopic examinations, each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip.
- For **complete blood counts**, each **measured** individual analyte that is ordered **and reported** is counted separately. Differentials are counted as one test.
- Do not count calculations (e. g., A/G ratio, MCH, and T7), quality control, quality assurance and proficiency testing assays).
- For **immunohematology**, each ABO, Rh, antibody screen, crossmatch or antibody identification is counted as one test.
- For **histopathology**, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains performed on slides to the total number of specimen blocks prepared by the laboratory.
- For **cytology**, each slide (not case) is counted as one test for both Pap smears and nongynecologic cytology.
- For **cytogenetics**, the number of tests is determined by the number of specimen types processed on each patient; e.g., a bone marrow and a venous blood specimen received on one patient is counted as two tests.
- For flow **cytometry** each measured individual analyte that is ordered and reported is counted separately.

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

❑ Initial Application ❑ Survey ❑ Change in Certification Type ❑ Other Changes	CLIA Identification Number _____D_____ *(If an initial application leave blank, a number will be assigned)*
Facility Name	Federal Tax Identification Number Telephone No. *(Include area code)* Fax No. *(Include area code)*
Facility Address — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing address is specified*	Mailing/Billing Address ***(If different from street address, include attention line and/or Building, Floor, Suite)***
Number, Street *(No P.O. Boxes)*	Number, Street
City State ZIP Code	City State ZIP Code
Name of Director *(Last, First, Middle Initial)*	For Office Use Only Date Received _____

II. TYPE OF CERTIFICATE REQUESTED *(Check one)*

❑ Certificate of Waiver *(Complete Sections I – VI and IX – X)*

❑ Certificate for Provider Performed Microscopy Procedures *(PPM) (Complete Sections I – X)*

❑ Certificate of Compliance *(Complete Sections I – X)*

❑ Certificate of Accreditation (Complete Sections I through X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes

❑ The Joint Commission ❑ AOA ❑ AABB
❑ CAP ❑ COLA ❑ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

III. TYPE OF LABORATORY *(Check the one most descriptive of facility type)*

- ❑ 01 Ambulance
- ❑ 02 Ambulatory Surgery Center
- ❑ 03 Ancillary Testing Site in Health Care Facility
- ❑ 04 Assisted Living Facility
- ❑ 05 Blood Bank
- ❑ 06 Community Clinic
- ❑ 07 Comp. Outpatient Rehab Facility
- ❑ 08 End Stage Renal Disease Dialysis Facility
- ❑ 09 Federally Qualified Health Center
- ❑ 10 Health Fair
- ❑ 11 Health Main. Organization
- ❑ 12 Home Health Agency
- ❑ 13 Hospice
- ❑ 14 Hospital
- ❑ 15 Independent
- ❑ 16 Industrial
- ❑ 17 Insurance
- ❑ 18 Intermediate Care Facility for Mentally Retarded
- ❑ 19 Mobile Laboratory
- ❑ 20 Pharmacy
- ❑ 21 Physician Office
- ❑ 22 Practitioner Other *(Specify)* _____
- ❑ 23 Prison
- ❑ 24 Public Health Laboratories
- ❑ 25 Rural Health Clinic
- ❑ 26 School/Student Health Service
- ❑ 27 Skilled Nursing Facility/ Nursing Facility
- ❑ 28 Tissue Bank/Repositories
- ❑ 29 Other *(Specify)* _____

IV. HOURS OF LABORATORY TESTING *(List times during which laboratory testing is performed in HH:MM format)*

	SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
FROM:							
TO:							

(For multiple sites, attach the additional information using the same format.)

V. MULTIPLE SITES *(must meet one of the regulatory exceptions to apply for this provision)*

Are you applying for the multiple site exception?

❑ No. If no, go to section VI. ❑ Yes. If yes, complete remainder of this section.

Indicate which of the following regulatory exceptions applies to your facility's operation.

1. Is this a laboratory that has temporary testing sites?
   ❑ Yes ❑ No

2. Is this a not-for-profit or Federal, State or local government laboratory engaged in limited (not more than a combination of 15 moderate complexity or waived tests per certificate) public health testing and filing for a single certificate for multiple sites?
   ❑ Yes ❑ No

   If yes, provide the number of sites under the certificate_____ and list name, address and test performed for each site below.

3. Is this a hospital with several laboratories located at contiguous buildings on the same campus within the same physical location or street address and under common direction that is filing for a single certificate for these locations?
   ❑ Yes ❑ No

   If yes, provide the number of sites under this certificate_____ and list name or department, location within hospital and specialty/subspecialty areas performed at each site below.

If additional space is needed, check here ❑ and attach the additional information using the same format.

NAME AND ADDRESS / LOCATION		TESTS PERFORMED / SPECIALTY / SUBSPECIALTY
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	
Name of Laboratory or Hospital Department		
Address/Location *(Number, Street, Location if applicable)*		
City, State, ZIP Code	Telephone Number ( )	

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Indicate the estimated TOTAL ANNUAL TEST volume for all waived tests performed _____

❑ Check if no waived tests are performed.

VII. PPM TESTING

Indicate the estimated TOTAL ANNUAL TEST volume for all PPM tests performed _____

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the "total estimated test volume" in section VIII.

❑ Check if no PPM tests are performed

VIII. NONWAIVED TESTING *(Including PPM testing)*

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the information included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY		_____	**HEMATOLOGY**		_____
❑ Transplant	_____		❑ Hematology	_____	
❑ Nontransplant	_____				
			IMMUNOHEMATOLOGY		_____
MICROBIOLOGY		_____	❑ ABO Group & Rh Group	_____	
❑ Bacteriology	_____		❑ Antibody Detection (transfusion)	_____	
❑ Mycobacteriology	_____		❑ Antibody Detection (nontransfusion)	_____	
❑ Mycology	_____		❑ Antibody Identification	_____	
❑ Parasitology	_____		❑ Compatibility Testing	_____	
❑ Virology	_____				
DIAGNOSTIC IMMUNOLOGY		_____	**PATHOLOGY**		_____
❑ Syphilis Serology	_____		❑ Histopathology	_____	
❑ General Immunology	_____		❑ Oral Pathology	_____	
			❑ Cytology	_____	
CHEMISTRY		_____			
❑ Routine	_____		**RADIOBIOASSAY**		_____
❑ Urinalysis	_____		❑ Radiobioassay	_____	
❑ Endocrinology	_____				
❑ Toxicology	_____		**CLINICAL CYTOGENETICS**		_____
			❑ Clinical Cytogenetics	_____	

TOTAL ESTIMATED ANNUAL TEST VOLUME _____

IX. TYPE OF CONTROL

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT	
01 Religious Affiliation	04 Proprietary	05 City	08 Federal
02 Private		06 County	09 Other Government
03 Other _____ *(Specify)*		07 State	_____ *(Specify)*

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)*	DATE

LIST OF TESTS PERFORMED IN THE FACILITY

Facility Name:	Date:
Facility Address:	City/State/Zip:
Name of Person Completing Form:	

****PLEASE LIST THE MANUFACTURER'S NAME AND MODEL OF THE INSTRUMENT OR MANUFACTURER'S NAME OF THE TEST KIT USED FOR PATIENT TESTING. FOR EXAMPLE, DO NOT LIST "HEMATOLOGY MACHINE" OR "STREP KIT". THIS WILL ENSURE THAT YOU WILL RECEIVE THE CORRECT CERTIFICATE BASED ON THE TESTS PERFORMED IN YOUR LABORATORY.

Name of Laboratory Test	****Name of Instrument or Kit Used for Testing	CPT Code

Bobby Jindal
GOVERNOR

STATE OF LOUISIANA
DEPARTMENT OF HEALTH AND HOSPITALS

Alan Levine
SECRETARY

CERTIFICATE OF WAIVER

Dipstick/tablet reagent urinalysis nonautomated, **CPT-81002**
Fecal occult blood, **CPT-82270 / G0107**
Enterix InSure Fecal Occult Blood Test, **CPT-82274 QW**
Gastric occult blood by Smith Kline Gastroccult Test, **CPT-82273 QW**
Gastric occult blood by Beckman Coulter Primary Care Diagnostics, **CPT-82273 QW**
Gastric occult blood by Aerscher Hemaprompt FG, **CPT-82273 QW**
Gastric pH by Beckman Coulter Primary Care Diagnostics, **CPT-83986 QW**
Ovulation test-visual color comparison, **CPT-84830**
Urine pregnancy test, visual color comparison, **CPT-81025**
Erythrocyte sedimentation rate, nonautomated, **CPT-85651**
pH Body Fluids by Nitrozine paper, **CPT-83986 QW**

BLOOD GLUCOSE TESTS

1. Devices cleared by FDA for home use, **CPT-82962**
2. Hemocue B-Glucose photometer, for glucose and tolerances
   a) Glucose, **CPT-82947 QW**
   b) Post glucose dose includes glucose, **CPT-82950 QW**
   c) Tolerance test, 3 specimens, includes glucose, **CPT-82951 QW**
   d) Tolerance test, each additional beyond 3 specimens, **CPT-82952 QW**
3. Hemocue Glucose 201 Microcuvettes and Glucose 201 Analyzer, for glucose and tolerances
   a) Glucose, **CPT-82947 QW**
   b) Post glucose dose includes glucose, **CPT-82950 QW**
   c) Tolerance test, 3 specimens, includes glucose, **CPT-82951 QW**
   d) Tolerance test, each additional beyond 3 specimens, **CPT-82952 QW**
4. LXN Duet glucose monitoring System for:
   a) Glucose, **CPT-82962**
   b) Fructosamine, **CPT-82985 QW**
5. LXN IN CHARGE Diabetes Control System for:
   a) Glucose, **CPT-82962**
   b) Fructosamine, **CPT-82985 QW**
6. LXN Fructosamine Test System, **CPT-82985 QW**
7. Medisense Products Precision Xtra Advanced Diabetes Management System for:
   a) Glucose, **CPT-82962**
   b) Ketones, **CPT-82010 QW**
8. Cygnus Inc Glucowatch Automatic Glucose Biographer, **CPT-pending**

HEMOGLOBIN TESTS

1. Cooper sulfate, nonautomated, **CPT-83026**
2. Hemocue Hemoglobin System, **CPT-85018 QW**
3. Hemocue Hb 301 System, **CPT-85018 QW**
4. Hemocue HB 201 DM Analyzing System, **CPT-85018 QW**
5. Hemocue Donor Hemoglobin Checker System, **CPT-85018 QW**
6. GDS Diagnostic HemoSite Meter, **CPT-85018 QW**
7. GDS Technology STAT-Site MHgb Test System, **CPT-85018 QW**
8. Biotest Hemoglobin Measuring System, **CPT-85018 QW**
9. EKF Diagnostics Hemo Control Measurement and Hemo Control Microcuvettes, **CPT-85018 QW**
10. ITC Hgb Pro Professional Hemoglobin Testing System, **CPT-85018 QW**
11. Biosafe Labortories, INC, Anemiapro Self Screener, **CPT-85018 QW**
12. Stanbio HemoPoint H2 Hemoglobin Measurement System, **CPT-85018 QW**

SPUN HEMATOCRIT

1. Spun microhematocrit, **CPT-85013**
2. Wampole STAT-CRIT hct., **CPT-85014 QW**
3. Micro Diagnostic Spuncrit, Model DRC-40 Infrared Analyzer, **CPT-85013 QW**
4. Separation Technology STI HemataSTAT II, **CPT-85013**
5. Separation Technology STI HemataSTAT Model C70, **CPT-85013**
6. StatSpin Technologies CritSpin, **CPT-85013**
7. Vulcon Technologies Microspin 24, **CPT-85013**
8. UltraCrit, **CPT-85013 QW**

ERYTHROCYTE SEDIMENTATION RATE (ESR)

1. Becton Dickinson Seditainer ESR System, **CPT-85651**
2. Polymedco SEDIPLAST WESTERGREN ESR, **CPT-85651**
3. Polymedco SEDIPLAST WINTROBE ESR, **CPT-85651**
4. All Nonautomated ESR Procedures, **CPT-85651 QW**

GLYCOSOLATED HEMOGLOBIN

1. Bayer (Ames) DCA 2000, Hbg A1C, **CPT-83036 QW**
2. Bayer DCA 2000+, **CPT-83036 QW**
3. Provalis Diagnostics Glycosal HbA1c Test, **CPT-83036 QW**
4. Provalis Diagnostics IN2IT In-Office Analyzer (II) A1C Prescription Home Use Test System, **CPT-85018 QW**
5. Provalis Diagnostics G5 II HBA1C Test System, **CPT-85018 QW**
6. Metrika A1cNow for Home Use, **CPT-85018 QW**
7. Metrika A1CNOW for Prescription Home Use, **CPT-85018 QW**
8. Metrika DRX Professional Use Hemoglobin A1c Test, **CPT-85018 QW**
9. Metrika A1C NOW, **CPT-85018 QW**
10. Metrika DRX HBA1C Prescription Home Use, **CPT-85018 QW**

11. Bio-Rad Micromat II Hemoglobin A1c Prescription Home Use Test, CPT-83036 QW
12. Cholestech GDX A1C Test (Prescription Home Use), **CPT-83036 QW**
13. Boehringer Manneheim Accu-Chek A1C Hemoglobin Test, **CPT-83036 QW**
14. LXN Fructosamine Test System, **CPT-83036 QW**
15. Axis-Shield Affirm AS100 Analyzer, CPT-83036 QW

COAGULATION SYSTEMS FOR PROTHROMBIN TIME

1. Roche Diagnostics CoaguCheck (PT-S Test Strips), **CPT-85610 QW**
2. Roche Diagnostics CoaguCheck PST, **CPT-85610 QW**
3. Roche Diagnostics CoaguChek S Systems (PT-S Test Strips), **CPT-85610 QW**
4. Roche Diagnostics CoaguChek S Systems **CPT-85610 QW**
5. Roche Diagnostics CoaguChek XS, **CPT-85610 QW**
6. Roche Diagnostics CoaguChek XS PST, **CPT-85610 QW**
7. Roche Diagnostics CoaguChek (for Professional Use), **CPT-85610 QW**
8. ITC Protime Microcoagulation System (Professional Use), **CPT-85610 QW**
9. ITC Protime Microcoagulation System (Prescription Home Use), **CPT-85610 QW**
10. ITC ProTime Microcoagulation System, **CPT-85610 QW**
11. AvoSure Pro and Avo Sure PT system, **CPT-85610 QW**
12. Lifescan Harmony INR Monitoring System (Prescription Home Use), **CPT-85610 QW**
13. Lifescan Harmony INR Monitoring System (Professional Use), **CPT-85610 QW**
14. Lifescan Rubicon Prothrombin Time Monitoring System (Prescription Home Use), **CPT-85610 QW**
15. Lifescan Rubicon Prothrombin Time Monitoring System (Professional Use), **CPT-85610 QW**
16. Hemosense Inratio System, **CPT-85610 QW**
17. Avocet Acusure System (Prescription Home Use), **CPT-85610 QW**
18. Avocet Avosure PT System (Prescription Home Use), **CPT-85610 QW**
19. Boehringer Mannheim CoaguChek (For professional Use), **CPT-85610 QW**
20. Boehringer Mannheim CoaguChek PST, **CPT-85610 QW**

URINE CHEMISTRIES AND ANALYZERS

1. B.M. Chemstrip Micral for Microalbumin, **CPT-83518 QW**
2. B.M. (Roche) Corp Chemstrip Mini UA Analyzer, **CPT-81003 QW**
3. Roche/B.M. Chemstrip 101 UA Analyzer, **CPT-81003 QW**
4. Roche Chemstrip 101 UA Analyzer for Microalbumin, **CPT-82044 QW**
5. Roche Diagnostics Chemstrip Micral Dipstick for Microalbumin, **CPT-82044 QW**
6. Bayer Clinitek 50 UA Chemistry, **CPT-81003 QW**
7. Bayer Clinitek 50 UA Chemistry for:
   a) Microalbumin, **CPT-82044 QW**
   b) HCG, **CPT-84703 QW**
   c) Creatinine, **CPT-82570 QW**
8. Diatech Diagnostics Uriscreen, Urine Catalase, **CPT-81007 QW**
9. TECO Diagnostics URITEK TC-101 Urine Strip Reader, **CPT-81003 QW**

10. Bayer Diagnostics/ MICROALBUTIX Reagent Strips for:
    a) Microalbumin, **CPT-82044 QW**
    b) Creatinine, **CPT-82570 QW**
11. Diagnostic Chemicals Immunodip Urinary Albumin Screen, **CPT-83518 QW**
12. Bayer Multistix Pro 10LS Reagent Strips for creatinine, **CPT-82570 QW**
13. Bayer Multistix Pro 11 Reagent Strips for creatinine, **CPT-82570 QW**
14. Bayer Multistix Pro 7G Reagent Strips for creatinine, **CPT-82570 QW**
15. Hypoguard Diascreen 50 Urine Chemistry Analyzer, **CPT-81003 QW**
16. ThermoBiostar PocketChem UA, **CPT-81003 QW**
17. Beckman Coulter ICON Microalbumin, **CPT-83518 QW**
18. Arkray PocketChem UA, **CPT 81003 QW**
19. TECO Diagnostics URS-1B, **CPT-81003 QW**
20. Bayer CLINITEK Microalbumin Reagent Strip, **CPT-82570 QW**
21. Bayer CLINITEK hCG Reagent Strip, **CPT-84703 QW**

BLOOD CHOLESTEROL AND LIPIDS

1. Chemtrak Accumeter, **CPT-82465 QW**
2. Advanced Care, Johnson & Johnson, **CPT-82465 QW**
3. B.M. (Roche) Accuchek Instant Plus, **CPT-82465 QW**
4. B.M. (Roche) Accutrend GCChol Test, **CPT-82465 QW**
5. ENA C.T. Total Cholesterol total Cholesterol test, **CPT-82465 QW**
6. ActiMed Laboratories ENA.C.T. Total Cholesterol Test (PDU), **CPT-82465 QW**
7. Cholestech L.D.X.system:
    a) Total cholesterol, **CPT-82465 QW**
    b) HDL Cholesterol, **CPT-83718 QW**
    c) Triglycerides, **CPT-84478 QW**
    d) Glucose, **CPT-82947 QW**
    e) Post glucose dose includes glucose, **CPT-82950 QW**
    f) Tolerance test, 3 specimens, includes glucose, **CPT-82951 QW**
    g) Tolerance test, each additional beyond 3 specimens, **CPT-82952 QW**
    h) ALT, **CPT-84460 QW**
    i) Lipid Profile, **CPT-80061 QW**
8. Lifestream Technologies cholesterol monitor, **CPT-82465 QW**
9. Lifestream Technologies Personal cholesterol monitor, **CPT-82465 QW**
10. Lifestream Technologies Resolution cholesterol monitor, **CPT-82465 QW**
11. Polymer Technology Systems (PTS) MTM BioScanner 1000, Total Cholesterol, **CPT-82465 QW**
12. PTS BioScanner Plus,
    a) Total Cholesterol, **CPT-82465 QW**
    b) HDL, **CPT-83718 QW**
    c) Triglcerides, **CPT-84478 QW**
13. PTS Cardiocheck Analyzer
    a) Total Cholesterol, **CPT-82465 QW**
    b) HDL, **CPT-83718 QW**
    c) Triglycerides, **CPT-84478 QW**

d) Lipid Profile, **CPT-80061 QW**

14. PTS Bioscanner for:
    a) HDL Cholesterol, **CPT-83718 QW**
    b) Blood Ketones, **CPT-82010 QW**
15. PTS Bioscanner 2000
    a) Panel K981493 for Cholesterol, CPT-82465 QW
    b) Panel K990688/A008 for Cholesterol, CPT-82465 QW
    c) Panel K990247, K993377 for HDL, CPT-83718 QW
    d) for Triglycerides, **CPT-84478 QW**
16. PTS Bioscanner Test Strips Cholesterol, **CPT-82465 QW**
17. PTS CardioChek PA Analyzer for:
    a) Cholesterol, **CPT-82465 QW**
    b) HDL Cholesterol, **CPT-83718 QW**
    c) Triglycerides, **CPT-84478 QW**
    d) Lipid Profile, **CPT-80061 QW**

CHEMISTRIES

1. Clearplan Easy Fertility Monitor, Lutenizing Hormone, **CPT – 82465 QW**
2. Unipath Clearplan Easy Fertility Monitor, estrone 3 glucoride, **CPT – 82679 QW**
3. Genua Menopause Monitor Test, Follicle Stimulating Hormone, **CPT-83001 QW**
4. Applied Biotech, Inc RU25 Plus FSH Menopause Test, **CPT-83001 QW**
5. KDK Corporation Lactate Prop System, Lactic Acid (Lactate), **CPT-83604 QW**
6. Applied Biotech, Inc Instacheck Menopause Predictor Test (FSH), **CPT-83001 QW**
7. Genosis Fertell Female Fertility Test (FSH), **CPT-83001 QW**
8. Pan Probe Biotech Earlydetect Menopause Test (FSH), **CPT-83001QW**
9. Chembio Sure Check Ovulation Predictor (LH), **CPT-83002 QW**
10. Inverness Medical Early Ovulation Predictor Stix, **CPT-83002 QW**

DRUG TESTING

1. STC Diagnostics Q.E.D. A150 Saliva Alcohol Test, **CPT-82055 QW**
2. STC Diagnostics Q.E.D. A350 Saliva Alcohol Test, **CPT-82055 QW**
3. DynaGen NicCheck I Test Strips for Nicotine and/or it's Metabolites, **CPT-80101 QW**
4. Phamatech at Home Drug Test Kits (For Models 9050, 9063, 9063T, 9064, 9068, 9068T, 9069, 9073, 9073T, 9074, 9078, 9078T, 9079, 9083, 9084, 9133, 9147T, 9150X, 9150T and 9175T), **CPT-80101 QW**
5. Phamatech at Work Drug Test (for Models 9147 AWT and 9177 AWT), **CPT-80101 QW**
6. Phamatech QuickScreen One Step (Amphetamine, Cocaine, Metamphetamine, Opiate, and/or PCP) Test, **CPT-80101 QW**
7. Phamatech QuickScreen at Home Drug Test (9149, 9150, 9171, and 9175), **CPT-80101 QW**
8. Phamatech QuickScreen Pro Multi Drug Screening Test (9177 & 9178), **CPT-80101 QW**
9. Worldwide Medical Corp First Check Home Drug Test (THC, THC-COC, THC-COC-OPI-MET), **CPT-80101 QW**
10. Worldwide Medical First Check Home Drug Test Panel 4, **CPT-80101 QW**
11. OraSure Technologies QED A-150 and QED A-350 Saliva Alcohol Test, **CPT-82055 QW**

12. Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test, CPT-**80101 QW**
13. ADC CLIA Waived Marijuana (THC) Test, **CPT-80101 QW**
14. ADC CLIA Waived Marijuana (THC) and Cocaine Test, **CPT 80101-QW**
15. ADC CLIA Waived Multiple Drug Test Card, **CPT-80101 QW**
16. Forefront Diagnostics DrugFree Home THC/COC Test Kit, **CPT-80101 QW**
17. Alatex Scientific Peace of Mind Multiple Drugs of Abuse Test, **CPT-80101 QW**
18. Advantage Diagnostic Corp Peace of Mind Home Drug Test, **CPT-80101 QW**
19. Advantage Diagnostic Advantage Multiple Drugs of Abuse, **CPT-80101 QW**
20. Advantage Diagnostic Multi DOA Test, **CPT-80101 QW**
21. Lifesign Home Drug Test, **CPT-80101 QW**
22. Princeton Biomeditech Accusign DOA 4, **CPT-80101 QW**
23. Princeton Biomeditech Accusign Stik, **CPT-80101 QW**
24. Princeton Biomeditech Accustik, **CPT-80101 QW**
25. Princeton Biomeditech Accustik DOA 4, **CPT-80101 QW**
26. Princeton Biomeditech Accustrip DOA 4, **CPT-80101 QW**
27. Princeton Biomeditech Accustrip, **CPT-80101 QW**
28. Princeton Biomeditech Lifesign Home Drug Test, **CPT-80101 QW**
29. Princeton Biomeditech Status DS DOS 4, **CPT-80101 QW**
30. Princeton Biomeditech Status DS MET, **CPT-80101 QW**
31. Princeton Biomeditech Status Stik, **CPT-80101 QW**

STREPTOCOCCUS ANTIGEN SCREENING TESTS

1. Genzyme Contrast Strep A, **CPT-87880 QW**
2. Genzyme OSOM Ultra Strep A Test, **CPT-87880 QW**
3. Quidel QuickVue In-Line Strep A, **CPT-87880 QW**
4. Quidel Quick Vue In-Line One-Step Strep A, **CPT-87880 QW**
5. Binax NOW Strep A Test, **CPT-87880 QW**
6. Wyntek Diagnostics OSOM Strep A Test, **CPT-87880 QW**
7. Wyntek Diagnostics OSOM Ultra Strep A Test, **CPT-87880 QW**
8. SmithKline ICON FX Strep A Test, **CPT-87880 QW**
9. Abbott Signify Strep A Test, **CPT-87880 QW**
10. BioStar Acceva Strep A Test, **CPT-87880 QW**
11. Meridian Diagnostics ImmunoCard STAT Strep A, **CPT-87880 QW**
12. Jant Pharmacal AccuStrip Strep A (II), **CPT-87880 QW**
13. Jant Pharmacal Corp Clinipak Strep A Rapid Test Strip, **CPT-87880 QW**
14. Becton Dickinson Link 2 Strep A Rapid Test, **CPT-87880 QW**
15. Mainline Technology Mainline Confirms Strep A Dots Test, **CPT-87880 QW**
16. Fisher HealthCare SureVue Strep A, **CPT-87880 QW**
17. Remel RIM A.R.C. Strep A Test, **CPT-87880 QW**
18. Princeton BioMediTech BioStrep A Test, **CPT-87880 QW**
19. Princeton BioMediTech Status First Strep A, **CPT-87880 QW**
20. Lifesign LLC Stratus Strep A, **CPT-87880 QW**
21. Polymedco Poly stat A (II), **CPT-87880 QW**
22. Polymedco Poly Stat Strep A Liquid Test, **CPT-87880 QW**
23. Quidel Quickvue Dipstick Strep A, **CPT-87880 QW**

24. Beckman Coulter Primary Care Diagnostics ICON FX Strep A Test Strep A Immunochemical Strep A Antigen Test, **CPT-87880 QW**
25. Beckman Coulter Primary Care Diagnostics ICON SC Strep A Test, **CPT-87880 QW**
26. Beckman Coulter Primary Care Diagnostics ICON DS Strep A, **CPT-87880 QW**
27. Beckman Coulter ICON DS Strep A, **CPT-87880 QW**
28. Beckman Coulter ICON SC Strep A, **CPT-87880 QW**
29. Acon Strep A Rapid Test Strip, **CPT-87880 QW**
30. Applied Biotech SureStep Strep A (II) (for Throat swab), **CPT-87880 QW**
31. Applied Biotech Surestep Exact Strep A Test, **CPT-87880 QW**
32. Acon Strep A Twist Rapid Test, **CPT-87880 QW**
33. DE Healthcare Products TruView Strep A Test, **CPT-87880 QW**
34. DE Helathcare Products TruView Strep A Dipstick Test, **CPT-87880 QW**
35. Henry Schein One Step+ Strep A Test, **CPT-87880 QW**
36. Henry Schein One Step+ Strep A Dipstick Test, **CPT-87880 QW**
37. Immunostics Immuno/Strep A Detector, **CPT-87880 QW**
38. Immunostics Detector Strep A Direct, **CPT-87880 QW**
39. Instant Technologies, iStrep Strep A, **CPT-87880 QW**
40. Germaine Laboratories Strep Aim Tower, **CPT-87880 QW**
41. Germaine Laboratories Strep Aim Rapid Dipstick Test, **CPT-87880 QW**
42. Instant Technologies iStep One Step Strep A, **CPT-87880 QW**
43. Permaxim Rediscreen Strep A Rapid Test, **CPT-87880 QW**
44. Sacks Medical Refuah Strep A Rapid Test, **CPT-87880 QW**
45. ICON DS Strep A, **CPT-87880 QW**
46. Stanbio QuStick Strep A, **CPT-87880 QW**
47. Stanbio Laboratory EZ-Well Strep A Rapid Device Test, **CPT-87880 QW**
48. SA Scientific SAS Strep A, **CPT-87880 QW**
49. Mckesson Medi-Lab Strep A Test, CPT-87880 QW
50. Mckesson Medi-Lab Performance Strep A Test Cassette, CPT-87880 QW
51. Mckesson Medi-Lab Performance Strep A Test Dipstick, CPT-87880 QW
52. Mckesson Strep A Cassette, **CPT-87880 QW**
53. Medi-Lab Performance Strep A Twist Rapid Test, **CPT-87880 QW**
54. Inverness Medical Clearview Strep A Exact II Dipstick, **CPT-87880 QW**
55. Inverness Medical BioStar Acceava Strep A Test, **CPT-87880 QW**
56. Inverness Medical, Signify Strep A Dipstick, **CPT-87880 QW**
57. Biotechnostix Rapid Response Strep A Rapid Test Device, **CPT-87880 QW**
58. Biotechnostix Rapid Response Strep A Rapid Test Strip, **CPT-87880 QW**
59. RAC Medical Clarity Strep A Rapid Test Strips, **CPT-87880 QW**
60. RAC Medical Clarity Strep A Twist Rapid Test Device, **CPT-87880 QW**
61. Cardinal Health SP Brand Rapid Test Strep A Cassette, **CPT-87880 QW**
62. Cardinal Health SP Brand Rapid Test Strep A Dipstick, **CPT-87880 QW**
63. Laboratory Supply Company (LSC) PEP Strep A Cassette Test, **CPT-87880 QW**
64. Laboratory Supply Company (LSC) PEP Strep A Dipstick Test, **CPT-87880 QW**
65. PEP Performance Enhanced Products Strep A Cassette Test, **CPT-87880 QW**
66. PEP Performance Enhanced Products Strep A Dipstick, **CPT-87880 QW**

HELICOBACTER PYLORI TESTS

1. Serim pyloritek Test Kit, **CPT-87077 QW**
2. Serim pyloritek VP Test Kit, **CPT-87077 QW**
3. Quidel Quick Vue One-Step H. pylori Test, **CPT-86318 QW**
4. Quidel QuickVue H.pylori gII, **CPT-86318 QW**
5. Delta West CLOtest, **CPT-87077 QW**
6. Smith Kline FlexSure HP, **CPT-86318 QW**
7. Myoscience GI supply HP-FAST, **CPT-87077 QW**
8. Myoscience GI supply, Div. Chek-Med Systems HP One, **CPT-87077 QW**
9. Boehringer Mannheim AccuStat H. pylori OneStep, **CPT-86318 QW**
10. Abbott FlexPack HP Test, **CPT-86318 QW**
11. Abbott TestPack Plus H. pylori, **CPT-86318 QW**
12. Abbott Signify H. pylori Whole Blood, **CPT-86318 QW**
13. ChemTrak AccuMeter (WB), **CPT-86318 QW**
14. Becton Dickinson LINK 2 H. pylori Rapid Test, **CPT-86318 QW**
15. Princeton BioMeditech BioSign H. pylor WB, **CPT-86318 QW**
16. LifeSign H. pylori WB, **CPT-86318 QW**
17. LifeSign Status H.pylori (WB), **CPT-86318 QW**
18. Applied Biotech SureStep H.pylori WB Test, **CPT-86318 QW**
19. Ballard Medical Products CLOtest, **CPT-87077 QW**
20. JANT Pharmacal H.pylori (WB), **CPT-86318 QW**
21. Remel RIM A.R.C. H.pylori (WB), **CPT-86318 QW**
22. Polymedco, Inc Poly stat H.pylori (WB), **CPT-86318 QW**
23. Trinity BioTech Uni-Gold H.pylori (WB), **CPT-86318 QW**
24. Beckman Coutler Primary Care Diagnostics Flexsure HP Test (WB), **CPT-86318 QW**
25. Beckman Coulter ICON HP Test, **CPT-86318 QW**
26. Medical Instruments Pronto Dry, **CPT-87077 QW**
27. Meridian BioScience ImmunoCard STAT! H. pylori WB Test, **CPT-86319 QW**
28. Meridian Bioscience Immunocard STAT! HpSA, **CPT-86319 QW**
29. Inverness Medical Clearview H. pylori Test, **CPT-86319 QW**
30. BTNX Inc Rapid Response H. pylori Rapid Test Device, **CPT-86319 QW**
31. Clarity H. pylori Rapid Test Device, **CPT-86319 QW**
32. Instant Technologies iScreen H. pylori Rapid Test Device, **CPT-86319 QW**
33. PerMaxim RadiScreen H. pylori Test Device, **CPT-86319 QW**
34. Wampole Laboratories Clearview H. pylori II, **CPT-86319 QW**
35. Alfa Scientific Designs Instant View H. pylori Whole Blood Rapid Test, **CPT-86319 QW**
36. Cardinal Health SP Brand Rapid Test H. pylori, **CPT-86319 QW**
37. Germaine Laboratories, Aimstep H. pylorie, **CPT-86319 QW**
38. De HealthCare Products Truview H. pylori Test, **CPT-86319 QW**
39. Henry Schein Onestep+ H. pylori Test, **CPT-86319 QW**
40. Acon helicobacter pylori Rapid Test Device, **CPT-86319 QW**
41. GI Supply, Div. Chek-Med Systems HP One, **CPT-86319 QW**
42. GI Supply HP-Fast, **CPT-86319 QW**
43. Roche Diagnostics AccuStat H. pylori OneStep, **CPT-86319 QW**
44. ChemTrak AccuMeter H. pylori Test, **CPT-86319 QW**

INFECTIOUS MONONUCLEOSIS

1. Wampole Mono-Plus (WB), **CPT-86308 QW**
2. Genzyme Contrast Mono (WB), **CPT-86308 QW**
3. Genzyme OSOM Mono Test, **CPT-86308 QW**
4. Genzyme Rapid Mono, **CPT-86308 QW**
5. Genzyme Sure-Vue Signature MONO Test (Whole Blood), **CPT-86308 QW**
6. Wyntek Diagnostics OSOM Mono (WB), **CPT-86308 QW**
7. Wyntek Signify Mono Test (WB), **CPT-86308 QW**
8. Seradyn Color Q Mono (WB), **CPT-86308 QW**
9. Princeton BioMeditech BioSign Mono WB, **CPT-86308 QW**
10. BioStar Acceava Mono II (WB), **CPT-86308 QW**
11. BioStar Acceava Mono Test, **CPT-86308 QW**
12. LifeSign UniStep Mono (WB), **CPT-86308 QW**
13. LifeSign Status Mono, **CPT-86308 QW**
14. Quidel Cards O.S. Mono (WB), **CPT-86308 QW**
15. Quidel Quickvue+ Infectious Mononucleosis (WB), **CPT-86308 QW**
16. Applied BioTech Sure Step Mone (WB), **CPT-86308 QW**
17. Applied Biotech One Step+ Mono Test, **CPT-86308 QW**
18. Applied Biotech Truview Mono Test, **CPT-86308 QW**
19. Jant Pharmacal Accutest Infectious Mononucleosis Test (WB), **CPT-86308 QW**
20. Meridian ImmunoCard STAT! Mono (WB), **CPT-86308 QW**
21. Remel RIM A.R.C. Mono Test, **CPT-86308 QW**
22. Polymedco, Inc. Polystat Mono, **CPT-86308 QW**
23. Clearview MONO Whole Blood, **CPT-86308 QW**
24. Immuno Detector BioSign Mono WB, **CPT-86308 QW**
25. PerMaxim RediScreen Mononucleosis (Whole Blood), **CPT-86308 QW**
26. RAC Medical Clarity MONO Mononucleosis Rapid Test Device (Whole Blood), **CPT-86308 QW**
27. Rapid Response Mononucleosis Rapid Test Device (Whole Blood), **CPT-86308 QW**
28. Instant Technologies iScreen Mononucleosis Rapid Test Device, **CPT-86308 QW**
29. ACON Mononucleosis Rapid Test Device, **CPT-86308 QW**
30. ACON Mononucleosis Rapid Test Strip, **CPT-86308 QW**
31. McKesson Medi-Lab Performance Infectious Mononucleosis Test, **CPT-86308 QW**
32. Inverness Medical, Clearview Mono-plus II, **CPT-86308 QW**
33. Inverness Medical, Signify Mono Test, **CPT-86308 QW**
34. Beckman Coulter, ICON Mono, **CPT-86308 QW**
35. Cardinal Health, SP Brand Rapid Test Mono, **CPT-86308 QW**
36. Henry Schein One Step+ Mono Test, **CPT-86308 QW**

LYME DISEASE ANTIBODIES

Wampole PreVue B. burgdorferi Antibody Detection Assay, **CPT-86618 QW**

BLOOD LEAD

ESA Biosciences LeadCare II Blood Lead Testing, CPT-pending

Collagen Type I Crosslink, N-Telopeptides (NTX)
Ostex International NTX Point of Care Prescription Home Use, CPT-82523 QW

INFLUENZA

1. Quidel QuickVue Influenza A/B, **CPT-87804 QW**
2. ZymeTx Zstatflu Test for Influenza Types A and B Viruses, CPT-87449 QW
3. BinaxNOW Flu A Test, **CPT-87804 QW**
4. BinaxNOW Flu B Test, **CPT-87804 QW**
5. Binax NOW Influenza A & B Test Nasopharyngeal (Np) Swab and Nasal Wash/Aspirate Specimens, **CPT-87804 QW**
6. SA Scientific SAS Influenza B Test, **CPT-87804 QW**
7. SA Scientific SAS Influenza A Test, **CPT-87804 QW**

RESPIRATORY SYNCTIAL VIRUS (RSV)

1. Binax NOW RSV Test, **CPT-87899 QW**
2. Integrated Biotechnology Quick Lab RSV Test, **CPT-87899 QW**
3. Fisher Scientific Sure-Vue RSV Test, **CPT-87889 QW**
4. Meridian Bioscience ImmunoCard STAT! RSV PLUS, CPT-87889 QW
5. Remel Xpect RSV, **CPT-87899 QW**
6. SA Scientific SAS RSV Test, **CPT-87899 QW**
7. SA Scientific SAS RSVAlert, **CPT-87899 QW**
8. Wampole Laboratories Clearview RSV, **CPT-87899 QW**

SEMEN
Embryotech Laboratories FertilMARQ Home Diagnostic Screening Test, **CPT-89300 QW**

VAGINAL FLUIDS

1. Litmus Concepts Fem Exam Test Card (Vaginal Swab) for:
   a) Combined Amines, **CPT-82120 QW**
   b) pH Test, **CPT-83986 QW**
2. FemTek pHEM-ALERT for vaginal pH, **CPT-83986 QW**
3. Quidel QuickVue Advance pH and Amines Test:
   c) Amines, **CPT-82120 QW**
   d) pH Test, **CPT-83986 QW**
4. Common Sense Ltd. Fem-V Test Kit for vaginal pH, **CPT-83986 QW**
5. Common Sense Ltd. VI-Sense Acidity Test Kit, **CPT-83986 QW**

OVULATION DETERMINATION

1. Stesans Maybe?Mom Mini Ovulation Microscope, **CPT- 87210 QW**
2. O2 Unlimited Donna Ovulation Tester, **CPT-87210 QW**

BLADDER TUMOR ANTIGEN

1. Bion Diagnostic Sciences BTA Stat Test (home use), **CPT-86294 QW**
2. Matritech, Inc. NMP22 BladerCheck Test for Professional and Prescription Home Use, **CPT-86294 QW**

HIV-1 ANTIBODY TESTS

1. Orasure Technologies OraQuick Rapid HIV-1 Antibody Test, **CPT-86701 QW**
2. Orasure Oraquick Rapid HIV-1 Test, **CPT-86701 QW**
3. Trinity BioTech Uni-gold Recombigen HIV Test, **CPT-86701 QW**
4. Trinity BioTech Uni-gold Recombigen HIV Test Whole Blood, **CPT-86701 QW**

CERTIFICATE OF PROVIDER PERFORMED MICROSCOPY PROCEDURES

(Can perform all waived tests and the tests listed below.)

1. Wet mounts, including preparations of vaginal, cervical, skin specimens, **CPT-Q0111**
2. Potassium Hydroxide (KOH) preparations, **CPT-Q0112**
3. Pinworm Examinations, **CPT-Q0113**
4. Fern Test, **CPT-Q0114**
5. Post-coital direct, qualitative exams of vaginal, cervical mucous, **CPT-Q0115**
6. Nasal Smears for Eosinophils, **CPT-89190**
7. Fecal Leukocyte Exam, **CPT-G0026**
8. Semen analysis for the presence and/or motility of sperm (excludes Huhner test), **CPT-G0027**
9. Urinalysis Microscopic only, **CPT-81015**
10. Urinalysis Nonautomated with Microscopy, **CPT-81000**
11. Urinalysis by two or three glass test, **CPT-81020**
12. Urinalysis Automated with Microscopy, **CPT-81001**